



Joint United Nations Programme on HIV/AIDS
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RECOMMENDATION

PROVISIONAL WHO/UNAIDS SECRETARIAT RECOMMENDATIONS ON THE USE OF COTRIMOXAZOLE PROPHYLAXIS IN ADULTS AND CHILDREN LIVING WITH HIV/AIDS IN AFRICA

Prophylactic treatment with cotrimoxazole can potentially enhance essential HIV care programmes in Africa by preventing several secondary bacterial and parasitic infections in people living with HIV/AIDS (PLHA). This intervention has been discussed at a UNAIDS/WHO consultation held in Harare, Zimbabwe on 29-31 March 2000. In view of the urgent need to preserve the health and well-being of HIV-infected individuals in Africa, where the HIV epidemic has its largest impact, WHO and the UNAIDS secretariat endorse the following as provisional recommendations:

RECOMMENDATION

Cotrimoxazole should be used for prophylaxis in adults and children living with HIV/AIDS in Africa as part of a minimum package of care.

OPERATIONAL ISSUES

Selection criteria

Cotrimoxazole prophylaxis should be offered to the following HIV-positive adults (defined as over the age of 13 years):

- all persons with symptomatic HIV disease (Stage 2, 3 or 4 of the provisional WHO classification of HIV infection and disease).
- asymptomatic individuals who have a CD4 count of 500 or less or total lymphocyte count equivalent
- pregnant women after the first trimester

Cotrimoxazole prophylaxis should be offered to all HIV-exposed infants from six weeks of age, using the following criteria:

- any child born to an HIV-infected woman irrespective of whether the woman received antiretroviral therapy in pregnancy.
- any child who is identified as being HIV infected within the first year of life by PCR, HIV serology or by a clinical diagnosis of HIV infection (according to WHO/national guidelines).
- children older than 15 months who have had a PCP event, have symptomatic HIV disease, an AIDS defining illness, or have CD4 percentage less than 15.

Where PCR or other special diagnostic tests are available, this can be used to confirm the diagnosis in children.

The use of CD4 counts or total lymphocyte counts is not recommended for consideration of the initiation of therapy in infants because these measurements are not predictive of the risk of acquiring PCP in infants less than one year of age.

DRUG REGIMENS

The following drug regimens are recommended:

Adults:

- one double strength tablet or two single strength tablets daily.

Children:

- cotrimoxazole syrup should be administered once a day on a daily basis,
- if syrup is unavailable, crushed tablets may be used.
- the health professional may switch from syrup to tablet to ensure ongoing access to medication.
- the recommended dose is 150mg TMP/m² SMX 750 mg/m²

Duration:

- prophylaxis should be lifelong in both adults and children over the age of 15 months.
- for infants up to 15 months of age, prophylaxis should continue until HIV infection has been reasonably ruled out and the risk of exposure has ceased.
- for children older than 15 months of age, prophylaxis should be continued if they have had PCP, have symptomatic HIV disease or an AIDS-defining illness, or a CD4 percentage less than 15.

Criteria for stopping:

In both adults and children prophylaxis should be stopped:

- in the event of occurrence of severe cutaneous reactions such as fixed drug reaction or Stevens Johnson syndrome, renal and/or hepatic insufficiency or severe hematologic toxicity.
- if antiretroviral agents become available and therapy results in restoration of CD4 count to 500 cells/mm³.

RECRUITMENT

- candidates for cotrimoxazole prophylaxis should be recruited from all levels of health care facilities, AIDS service organizations and non-governmental organizations.
- initially prophylaxis should be prescribed by trained health care personnel.
- counselling should be provided.

FOLLOW UP

- cotrimoxazole prophylaxis should be used where regular follow-up of patients is possible
- in adults, follow-up should be initially every month and then every three months, if the medication is well tolerated.
- children should be evaluated on a monthly basis.
- adults and children should be monitored for toxicity, adverse clinical events and adherence.

- monitoring in adults should also include measurements of haemoglobin and white blood counts every six months, where facilities are available, or when clinically indicated.

DRUG SUPPLY

- medication should be supplied through existing drug distribution systems.
- governments should ensure an uninterrupted drug supply for both treatment and prophylaxis through estimating need and extra budgetary allocation.
- the quality of all formulations of cotrimoxazole should be ensured through regular monitoring.
- countries should be encouraged to supply the drug free of charge or at subsidised rates when possible.
- the private sector including industry and other medical insurance plans should be encouraged to provide cotrimoxazole prophylaxis.

TRAINING AND EDUCATION

- education and training of health care providers should occur at all levels.
- patients, care givers and communities should be made aware that prophylaxis is not a cure for HIV disease but that it is part of a package of care and support for people with HIV infection.
- advocacy for the use of cotrimoxazole prophylaxis should be established through consensus meetings of all stakeholders including the private health sector.

MONITORING AND EVALUATION

It is recommended that implementation of cotrimoxazole prophylaxis at country level be carefully monitored as there is limited experience in its use among people living with HIV/AIDS in Africa. Cotrimoxazole is widely used for other clinical indications, giving rise to concerns about exacerbation of antimicrobial resistance in the management of pneumonia in children, dysentery and malaria.

Monitoring should include:

- collection of **baseline data** as an aid to subsequent evaluation of the intervention's effectiveness. If and where the technical capacity necessary to collect such data is not available, data collection would still be possible in specific sentinel sites or specific cohorts.
- institution of ongoing surveillance for:
 1. clinical effectiveness of cotrimoxazole prophylaxis for people living with HIV/AIDS
 2. the impact of the cotrimoxazole prophylaxis on levels of antimicrobial resistance among target opportunistic pathogens.
 3. overall rates of antimicrobial resistance to cotrimoxazole
 4. clinical effectiveness of therapy of malaria with sulfamethoxazole-pyrimethamine

5. clinical effectiveness of cotrimoxazole in the therapy of other non-HIV illnesses
6. overall rates of reported and cumulative toxicity

FURTHER RESEARCH

Further research related to the use of cotrimoxazole for the prevention of opportunistic infections among PLHA in Africa should focus on:

- the identification of affordable alternatives to cotrimoxazole.
- the definition of optimal timing of initiation of cotrimoxazole prophylaxis in relation to stage of HIV infection and CD4 counts.
- the evaluation of effectiveness of cotrimoxazole prophylaxis in children older than one year.
- the cost-effectiveness of cotrimoxazole prophylaxis in PLHA in different areas in Africa in relation to timing and duration of prophylaxis
- willingness and ability to pay at the household level for cotrimoxazole prophylaxis
- impact on household income, savings and expenditures

The report of the consultation will be available in late 2000, at which time the provisional recommendations will also be submitted for publication to the WHO's Weekly Epidemiological Record.